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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,133	06/12/2006	Gyorgyi Verezkeyne Donath	1060-0164PUS1	1179
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BIRCH STEWART KOLASCH & BIRCH			EXAMINER	
PO BOX 747			SOLOLA, TAOFIQ A	
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
			1625	
			NOTIFICATION DATE	DELIVERY MODE
			11/02/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/563,133

Applicant(s)

VERECZKEYNE DONATH ET AL.

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 12-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 12 and 13 is/are rejected.
- 7) ☐ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1</u> | 6) <input type="checkbox"/> Other: ____ |

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Claims 12-15 are pending in this application.

Claims 1-11 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims lack adequate support in the specification. A and B types solvents are defined in the specification, page 7, by examples. However, "[e]xemplification is not an explicit definition." The specification must set forth the definition explicitly and clearly, with reasonable clarity, deliberateness and precision, *Teleflex Inc. v. Ficosa North Am Corp.*, 63 USPQ2d 1374, (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1854 (Fed. Cir. 2001).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 12 requires one to read the specification into the claim contrary to several precedent decisions by US courts and official practice. By replacing "A" and "B" type solvents with the specific solvents the rejection would be overcome.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 13 recites the broad recitation solvents, and the claim also recites preferably, more preferably, and most preferably solvents which are the narrower statements of the range/limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-13, are rejected under 35 U.S.C. 103(a) as being unpatentable over Lifshitz-Liron et al., WO 03/051362 A2.

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Applicant claims a process of making polymorph I of compound I, comprising dissolving the base in type A solvent, adding sulfuric acid in type A or B solvent, followed by type B solvent containing polymorph I of compound I (seeding) to form a precipitate of the product. In preferred embodiments type A solvent is acetone, and type B is diethyl ether.

Determination of the scope and content of the prior art (MPEP 2141.01)

Lifshitz-Liron et al., teach a similar process wherein type A solvent is acetone and type B is diethyl ether. The product is left to precipitate without seeding.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Lifshitz-Liron et al., is that applicant claims seeding the reaction mixture. Also, Lifshitz-Liron et al., do not teach using type B solvent to add sulphuric acid.

Finding of prima facie obviousness--rational and motivation (MPEP 2142.2413)

However, Lifshitz-Liron et al., teach acceleration of crystallization by seeding, which is well known in the art of crystallization. See page 24, line 1. Using type B solvent to add sulfuric acid is an obvious modification available to the preference of an artisan. Therefore, the instant invention is prima facie obvious from the teaching of Lifshitz-Liron et al. One of ordinary skill in the art would have known to seed the reaction mixture at the time the invention was made. The motivation is from the teaching of Lifshitz-Liron et al., and because it is well known in the art of crystallization process.

Alternatively, given the teaching of Lifshitz-Liron et al., that the precipitate takes between 45 minutes to 8 hours, that seeding is well known to accelerate crystallization procedures and Lifshitz-Liron et al., teach seeding is applicable in the process, it would have been obvious to try seeding at the time the invention was made.

When there is motivation

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to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct 1727,-----, 82 USPQ2d 1385, 1397 (2007).

Alternatively, given the common practice of using seeding in crystallization procedures and/or the teaching of the prior art, one of ordinary skill faced with the need to accelerate crystallization of the product would have known to use seeding, at the time the invention was made. "When a work is available in one field of endeavour, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technology is obvious unless its actual application is beyond his or her skill." "One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007).

Alternatively, the instantly claimed process and seeding thereof are not applicant's invention. They are in the public domain prior to the time the instant invention was made. Applicant has done no more than combine separate but well-known inventions. While the combination may perform a useful function it did no more than what they would have done

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separately. *In re Anderson*, 396 U.S. 57, 163 USPQ 673 (1969) cited in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007). When a patent simply arranges old elements with each performing the same function it had been known to perform and yields predictable result, the combination is obvious. *In re Sakraida*, 425 US 273, 189 USPQ 449 (1976) cited in *KSR, supra*. A patent for such combination "obviously withdraws what is already known into the field of its monopoly." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 187 USPQ 303 (1950), cited in *KSR, supra*.

Objection

Claims 14-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Specification

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. For examples, see page 3, paragraph 2, page 5, last 3 lines, page 13, last 3 lines and page 14, line 1.

The specification cites several patent applications, which are not incorporated by reference per the MPEP which states:

A mere reference to another application, publication or patent is not an incorporation of anything therein into the application containing such reference for the purpose of satisfying the requirement of 35 USC 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). Particular attention should be directed to the subject matter and the specific portions of the referenced document where the subject matter being incorporated may be found. MPEP 608.01(p).

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If the document is a pending US application: prior to allowance of an application that incorporates essential material by reference to a pending US application, if the referenced application has not been published or issued as a patent, applicant is required to amend the disclosure of the referencing application to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating the amendment consists of the same material incorporated by reference in the referencing application. MPEP 608.01(p).

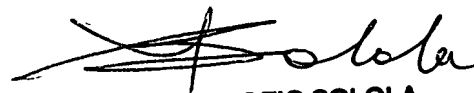
Applicant should note that incorporation of a foreign document, which is not published in English language, is not allowed.

The substitute specification filed must be accompanied by a statement that it contains no new matter.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


TAOFIQ SOLOLA
PRIMARY EXAMINER

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October 24, 2007